



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Opioid Analgesic Prescriber Education and Training Opportunities to Prevent Opioid Overdose and Opioid Use Disorder

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for Information.

SUMMARY: Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics – a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain – have been increasingly implicated in drug overdose deaths over the last decade. Alarming, deaths related to opioid analgesic overdose have quadrupled since 1999, and this increase in deaths has been linked to parallel increases in opioid prescribing. As part of its comprehensive response to the opioid epidemic, HHS is actively working to stem overprescribing of opioids in a number of ways, including by providing clinicians with the tools and education they need to make informed prescribing decisions. In particular, HHS has developed a number of activities that support opioid analgesic prescriber education. This Request for Information (RFI) seeks comment on the most promising approaches in prescriber education and training programs and effective ways to leverage HHS programs to implement/expand them.

DATES: Comments must be received at one of the addresses provided below, no later than 5p.m. on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- Federal eRulemaking Portal: You may submit electronic comments at <http://www.regulations.gov>. Follow the instructions for submitting electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.
- Regular, Express, or Overnight Mail: You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.
- Hand Delivery or Courier: If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, Attention: 1557 RFI (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)
- Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Office of the Assistant Secretary for Planning and Evaluation, 202-690-7858.

SUPPLEMENTARY INFORMATION:

I. Background

Education and training in pain management and appropriate opioid analgesic prescribing, including how to identify patients who may be at risk for opioid misuse and ensuring patients

treated with opioids receive the appropriate dose and quantity of medication for their condition, are key elements of the response to the opioid epidemic. Surveys of healthcare providers indicate that they receive inadequate training on pain management, and many feel uncomfortable managing patients with pain. In addition, research has identified significant gaps and fragmentation in pain education in health professional schools, and the National Pain Strategy indicates that health professional education is a central component of advancing a system of care in which all people receive high quality and evidence-based pain care.

To improve education and training on pain management and appropriate opioid prescribing, HHS has developed programs that engage prescribers throughout their training and professional career. For example, in an effort to educate health professional students, the National Institutes on Drug Abuse (NIDA) coordinates the National Institutes of Health Pain Consortium's Centers of Excellence in Pain Education that develop and distribute pain management curriculum resources for medical, dental, nursing, and pharmacy schools.

Many HHS training initiatives target practicing clinicians throughout their learning and practice lifecycles. Some programs, such as NIDA's NIDAMED program, offer opioid and pain management training as continuing education credit opportunities. Additionally, the Food and Drug Administration (FDA) has put in place a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications. The ER/LA Opioid Analgesic REMS requires manufacturers to make prescriber training available through accredited continuing education (CE) programs funded by the ER/LA sponsors. To assure that the training is balanced and to protect from industry influence, the training is based upon the FDA blueprint for Prescriber Education for ER/LA opioids and is made available through third-party CE providers.

Other programs utilize a peer-to-peer mentoring model. The Substance Abuse and Mental Health Services Administration's Providers' Clinical Support System for Opioid Therapies (PCSS-O) is one such model that offers colleague support and mentoring as well as evidence-based educational resources on how to effectively utilize opioid analgesics for patients with pain and patients with opioid use disorders. And, other resources are intended to support decision

making during an active patient encounter. The Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain facilitates providers' decision-making regarding appropriate pain treatment for patients 18 years and older in the primary care setting.

II. Solicitation of Comments

This RFI is seeking comment on the range of approaches to educating and training providers on pain management and appropriate opioid analgesic prescribing, including identifying patients at risk for abuse and prescribing the appropriate dose and quantity of medication for their condition. As noted above HHS has undertaken several programs to engage providers on these topics, and this RFI is meant to solicit input not only on those but also on other approaches. For example, HHS seeks comment on the impact of non-federal prescriber training policies or programs on opioid analgesic prescriber competency:

- how states have developed, promoted, and made pain management and opioid analgesic prescriber education available,
- whether state requirements for mandatory pain management and opioid prescribing training have led to any changes in prescriber behavior and/or other outcomes as a result of these programs,
- the challenges opioid education providers have faced in implementing opioid prescriber education initiatives,
- which measures education providers use to evaluate the success of their interventions, or
- how health information technology has been implemented to assist the prescriber in appropriate opioid prescribing and pain management.

HHS also is soliciting suggestions for additional activities the Department could implement to ensure universal prescriber education on appropriate pain management and opioid prescribing.

For example, additional HHS activities could include:

- adding new opioid prescriber education to Medicare Conditions of Participation and/or to Medicare enrollment requirements,
 - adding quality measures around safe opioid use to the specialty core measures that clinicians may choose to report under the Merit-based Incentive Payment System (MIPS),
- or

- revising the ER/LA Opioid Analgesic REMS to require that prescribers of opioids receive appropriate training on pain management and safe opioid use before being able to prescribe specific opioids.

Finally, HHS seeks feedback through this RFI on the ability of existing HHS education and training programs to educate all opioid analgesic prescribers on appropriate pain management and opioid prescribing including comments on the development and delivery of the content and on efforts to assess the impact of the training initiatives.

III. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble.

Dated: June 29, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

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